

**USUHS FORM 3208**  
**ASSURANCE SUPPLEMENT FORM**  
(new, competing continuation, supplemental and revision protocols)

REA Date Stamp

**Project Number:** \_\_\_\_\_  
(REA will assign)

**Project Title:** \_\_\_\_\_  
(For NIH submissions do not exceed 56 characters)

**SECTION A: PRINCIPAL INVESTIGATOR INFORMATION**

<b>1. Name (Last, First, MI):</b>			
<b>2. Degree(s):</b>			
<b>3. Academic Title/ Military Rank</b>			
<b>4. Percent Effort on this project:</b>	% (Effort on awarded projects and other activities may not exceed 100%)		
<b>5. USUHS Department:</b>			
<b>6. Telephone:</b>	<b>Office:</b>	<b>Fax:</b>	<b>E-mail:</b>
<b>7. USUHS Building/ Room No.</b>			
<b>8. Off-Site Address:</b>			
<b>9. PI's Source of Salary:</b>	<input type="checkbox"/> <b>USUHS</b> <input type="checkbox"/> <b>AFRRI</b>		
	<input type="checkbox"/> <b>Henry M. Jackson Foundation (HJF)</b>		
<b>Billet No./Organization: (if known)</b>	<input type="checkbox"/> <b>Other Foundation (name):</b> _____		
_____	<input type="checkbox"/> <b>Other Federal/ Military (name):</b> _____		

**SECTION B: SIGNATURES**

*I certify that I will undertake the attached protocol if awarded and that assurance(s) will be obtained from the responsible individual(s) at the performance site(s) indicated before any work begins. As the Principal Investigator, I assume full responsibility for: 1) the scientific soundness, accuracy, and completeness of the research proposal, 2) the scientific, ethical, and technical aspects of any resulting research project, 3) the proper budgetary management of awarded funds, 3) complying with specific Sponsor terms and conditions and USUHS policies and 4) protecting the University from legal liability related to the research project as outlined in Appendix 1.*

\_\_\_\_\_  
**Principal Investigator (signature)**

\_\_\_\_\_  
**Date**

*I have reviewed this protocol, approve the content, and certify that adequate resources and facilities are available to support this research effort.*

\_\_\_\_\_  
**USUHS Department Chair (signature)**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**USUHS Department Chair (signature)**

\_\_\_\_\_  
**Date**

(Second chair's signature is required if two departments are involved. If additional chair's signature is required, add additional sheet)

**For REA use only**

*I have reviewed this protocol and approve the content..*

\_\_\_\_\_  
**USUHS Vice President for Research**

\_\_\_\_\_  
**Date**

## SECTION C: PROJECT INFORMATION

<b>1.</b>	Application Due Date: _____										
<b>2.</b>	Project Type: <input type="checkbox"/> New <input type="checkbox"/> Competing Continuation <input type="checkbox"/> Supplemental										
<b>3.</b>	Is this a revised application? <input type="checkbox"/> Yes <input type="checkbox"/> No      If yes, list the previous project number: _____										
<b>4.</b>	Anticipated Period of Performance:      Project Start: _____ Project End: _____										
<b>5.</b>	<p>List performance sites and indicate percentage of the work being performed at each site:</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; border-bottom: 1px solid black;">Performance Site (Should not exceed 100%)</th> <th style="text-align: left; border-bottom: 1px solid black;">% of Work</th> </tr> </thead> <tbody> <tr> <td>USUHS (on-campus space and/or rented off-campus space)</td> <td>_____</td> </tr> <tr> <td>Other off-site location(s): _____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> <tr> <td>_____</td> <td>_____</td> </tr> </tbody> </table>	Performance Site (Should not exceed 100%)	% of Work	USUHS (on-campus space and/or rented off-campus space)	_____	Other off-site location(s): _____	_____	_____	_____	_____	_____
Performance Site (Should not exceed 100%)	% of Work										
USUHS (on-campus space and/or rented off-campus space)	_____										
Other off-site location(s): _____	_____										
_____	_____										
_____	_____										
<b>6.</b>	<p>What is the funding source?</p> <p><input type="checkbox"/> USUHS Intramural</p> <p><input type="checkbox"/> DoD Federal (specify): _____</p> <p><input type="checkbox"/> Non-DoD Federal (specify): _____</p> <p><input type="checkbox"/> Non-Profit (specify): _____</p> <p><input type="checkbox"/> For-Profit (specify): _____</p>										
<b>7.</b>	Does the Sponsor allow for indirect cost? <span style="float: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</span>										
<b>8.</b>	If yes what is the allowable rate? <span style="float: right;">Percent (%)</span>										
<b>9.</b>	Review Appendix 1 of the USUHS Form 3208 Guidelines, Project Description List. Choose a single category that best describes your project and enter the code and corresponding category below.										
<b>a.</b>	Code (number and letters, ie. 1a) _____										
<b>b.</b>	Category (description, ie. Behavioral) _____										
<b>c.</b>	Other (if your research does not fall into any of the categories listed) _____										
<b>10.</b>	<p>Select a single category that describes the science of this project:</p> <p><input type="checkbox"/> Basic Science                      <input type="checkbox"/> Clinical Science</p> <p><input type="checkbox"/> Other (Describe): _____</p>										
<b>11.</b>	<p>Have additional resources (personnel, space, equipment), not covered by the funding of this research, required for the conduct of this project been identified and made available by the chairperson? <span style="float: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</span></p> <p>(If yes, submit a letter from your chair outlining the resources)</p>										
<b>12.</b>	<p>Does this project include USUHS paid employees? <span style="float: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</span></p> <p>If yes, list the employees ( Do not list yourself here) (Use an additional sheet if needed):</p> <p>_____</p> <p>_____</p> <p>_____</p>										
<b>13.</b>	Is there scientific or budgetary overlap with other research projects under your direction? If yes, explain on a separate sheet. <span style="float: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</span>										
<b>14.</b>	Does this project involve any classified information? (Contact the USUHS Security Office for guidance) <span style="float: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</span>										
<b>15.</b>	Does this project involve research with foreign entities? (Contact the Clinical Affairs Office for guidance) <span style="float: right;"><input type="checkbox"/> Yes      <input type="checkbox"/> No</span>										

## SECTION D: ASSURANCE COMPLIANCE

### IRB

1. **Does this project involve human research?** (including human cells, tissues or fluids, surveys or database use or development) (Submit the USUHS Form 3204: Research Involving Human Subjects (new or modification/addendum) with the application to REA, Room A1032). ☐ Yes ☐ No
2. **Does this project require immediate IRB review?** (no funds required or needs approval to accompany application) ☐ Yes ☐ No
3. **Does this project involve human research at a non-USUHS location(s), including AFRRRI? If yes, list the location(s) below:** ☐ Yes ☐ No  
 Location 1: \_\_\_\_\_  
 Location 2: \_\_\_\_\_  
 Location 3: \_\_\_\_\_

### IACUC

4. **Does this project involve animal research at USUHS?** ☐ Yes ☐ No
5. **Have you submitted the proper animal protocol form to DLAM? If yes, provide the Animal Protocol Title and number.** ☐ Yes ☐ No  
 Animal Protocol Title: \_\_\_\_\_  
 Animal Protocol Number: \_\_\_\_\_
6. **Check the applicable box and submit the form to DLAM.**  
☐ USUHS Form 3206 Animal Study Proposal Form  
☐ USUHS Form 3206A Animal Study Protocol (annual review)  
☐ USUHS Form 3206B Animal Study Protocol (modification/addendum)  
☐ USUHS Form 3206C Conveyance with Standard Animal Use Procedure
7. **Does this project involve animal research at a Non-USUHS location, including AFFRI? If yes, list the location(s) below:** ☐ Yes ☐ No  
 Location 1: \_\_\_\_\_  
 Location 2: \_\_\_\_\_  
 Location 3: \_\_\_\_\_

### BIOSAFETY

8. **Do you require a Certificate of Environmental Safety to accompany this proposal submission? If yes, list labs to be used:** ☐ Yes ☐ No
9. **Do you require a Recombinant DNA approval to accompany this proposal submission?** ☐ Yes ☐ No
10. **Do you require a Radiation Safety approval to accompany this proposal submission?** ☐ Yes ☐ No

#### Environmental Safety Certificate

11. **Does this project involve any of the following safety hazards? (Mark all that apply)** ☐ Yes ☐ No  

☐ Dangerous Materials  
☐ Class 3 or 4 Lasers  
☐ Human Blood, Tissue, or Body Fluids

☐ Controlled Substances  
☐ High Intensity (>85 decibels) Sound  
☐ Other: \_\_\_\_\_

☐ Extremely Hazardous Chemicals  
(If you checked this box please attach a list.)
12. **Have you discussed this requirement with the Pharmacy?** ☐ Yes ☐ No

#### Recombinant DNA or DNA

13. **Does this project involve the use of recombinant preparations and/or CDC select agents?** ☐ Yes ☐ No

#### Radioactive Materials

14. **Does this project involve the use of radioactive materials?** ☐ Yes ☐ No

#### Anatomic Material Use Committee

15. **Does your research involve the use of human cadaver material?** ☐ Yes ☐ No

## APPENDIX 1

### ROLES AND RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS FOR RESEARCH PROJECTS

When undertaking a research project, the Principal Investigator assumes numerous important responsibilities that include the preparation of the proposal, the compliance with appropriate assurance processes, the conduct and integrity of the scientific project and its close-out processes, and the subsequent dissemination of the research results.

The Principal Investigator is responsible for:

**-the scientific soundness, accuracy, and completeness of the research proposal including**

Preparation of the technical research proposals or research fellowship applications;  
Submission of these proposals through REA with the proper scientific, statistical, and departmental review and the verification of the adequacy of the resources to conduct the research; and  
Coordinating proper review of any off-site research activity.

**-the scientific, ethical, and technical aspects of any resulting research project including**

Oversight of all activities in the laboratory and each study site involved;  
Training and education of all individuals working on the research project in such areas as laboratory safety, scientific rigor, data collection and management, and scientific integrity including, but not limited to, issues such as authorship, conflict of interest and commitment, and humans and animal subjects issues; and  
Understanding that research conducted at USUHS must satisfy not only the needs of the investigators but of the institution, society, and the funding agency.

**-the proper budgetary management of awarded funds including**

Authorizing the allocation and verifying the appropriateness of research costs as legitimate, allowable, and correct;  
Financial monitoring of accelerated expenditures, large unobligated balances, and over expenditures;  
Initiation and coordination of personnel actions for the research personnel;  
Re-budgeting in a timely and accurate way; and  
Ensuring that program income (if any) is returned to the research project.

**-compliance with the specific terms of the award and statutes including**

Obtaining, maintaining, and adhering to all research assurances such as human subjects, animal care and welfare, radiation safety, hazardous chemicals, recombinant DNA, and biological substances;  
Compliance with terms including prior written approval for change in scope, foreign travel, equipment purchases and disposition, hiring, contracting, and re-budgeting; and  
Submitting interim and final scientific reports and other required reports to REA for submission to the funding organization.

**-protecting the University from legal liability related to the research project**

**-following other Federal regulations**

Such as those concerning proscriptions against lobbying, financial discussions with industry funding sponsors, and as specified in the USUHS Grant Terms and Conditions.